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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,913	01/10/2006	Konsei Shino	900-539	5635

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EXAMINER
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CUMBERLEDGE, JERRY L

ART.UNIT	PAPER NUMBER
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3733

DATE MAILED: 10/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/563,913

Applicant(s)

SHINO, KONSEI

Examiner

Jerry Cumberledge

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 1/10/06.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

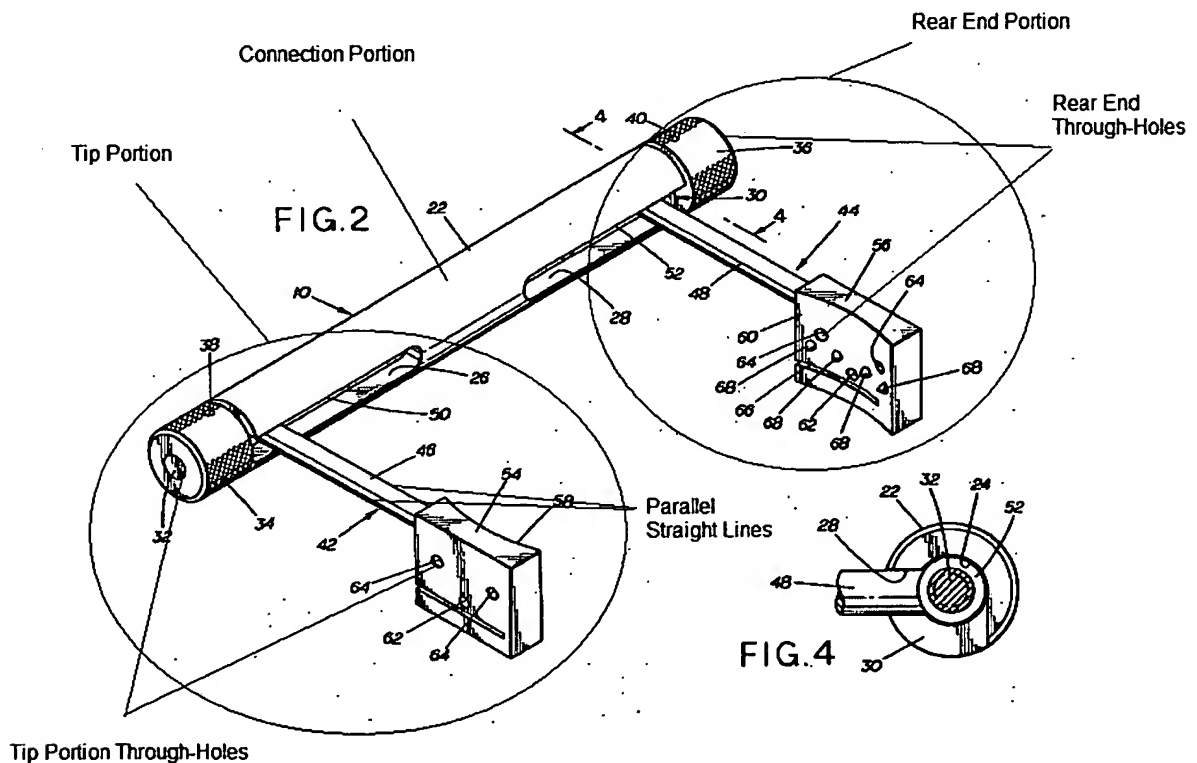
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

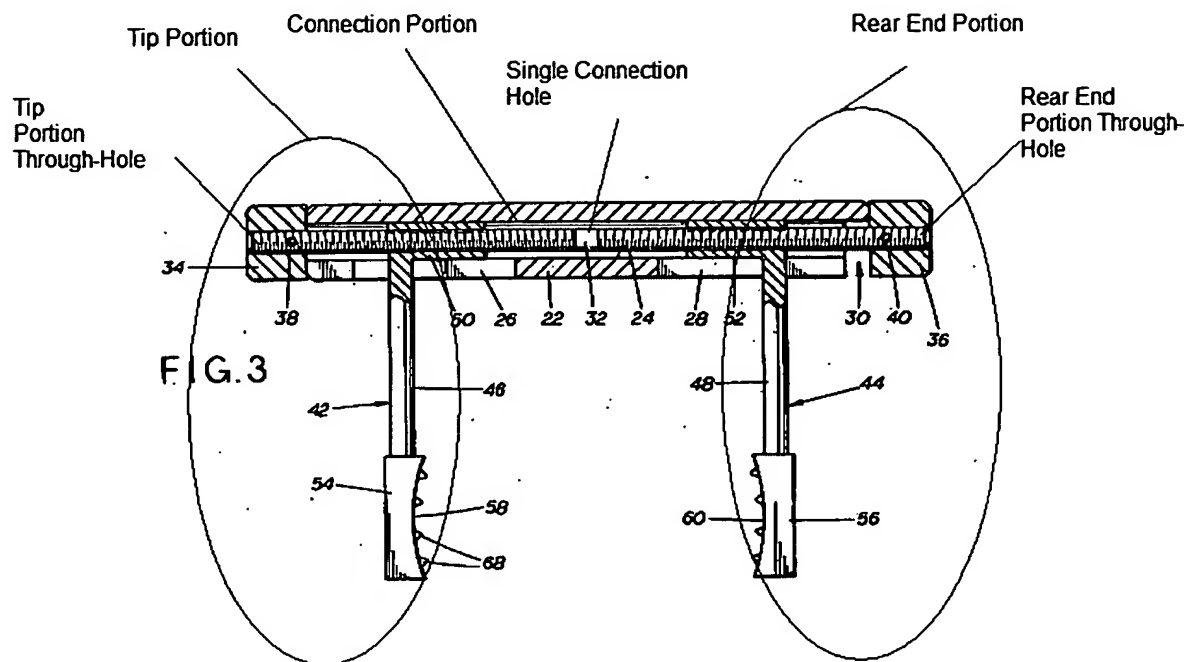
Claims 1, 3, 8, 9 and 10-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoffman et al. (US Pat. 5,021,056).

Hoffman et al. disclose a device for ligament reconstruction comprising: a tip portion (Fig. 2 below) having two parallel through-holes (Fig. 2 below) formed therein in juxtaposition; a rear end portion having two through-holes (Fig. 2 below and Fig. 3 below) formed therein in juxtaposition coaxially with the two through-holes of the tip portion; and a connection portion (Fig. 2 below) connecting the rear end portion and the tip portion and having a single connection hole (Fig. 3 below) connecting one of the through-holes of the tip portion coaxially to one of the through-holes of the rear end portion, the connection portion being thinner and longer than the tip portion and the rear end portion (Fig. 3), wherein the tip portion has a generally elliptical (Fig. 2, the portion of rod 46) or rectangular cross section (rectangular, Fig. 2, ref. 54) elongated in a direction in which the through-holes thereof are juxtaposed, so that the tip portion is capable of being driven into an articular bone to form a flat socket in the bone by hitting the rear end portion.

The elliptical cross section is of a generally oval shape or a racetrack-like elliptical shape. The cross section of rod 46 is a circle, and circles are ellipses. The racetrack-like elliptical shape is defined by a pair of parallel straight lines (Fig. 2 below) and a pair of semicircles connecting opposite ends of the straight lines. The semicircles are the two curved surfaces that extend around the rod 46 and connect the parallel straight lines. The connection portion has a generally round or oval cross section (Fig. 2, ref. 22). The device is capable of performing reconstruction of an anterior cruciate ligament graft.

Hoffman et al. further disclose drills (column 5, lines 16-18) and guide pins (column 3, lines 33-34).





With regard to statements of intended use and other functional statements (e.g. "...for ligament reconstruction...", "...reconstruction of an anterior cruciate ligament graft..."), they do not impose any structural limitations on the claims distinguishable over the device of Hoffman et al., which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

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The device of Hoffman et al. is capable of performing a method for ligament reconstruction utilizing a ligament reconstruction device as recited in claim 1, the method comprising the steps of: drilling a guide pin into an articular bone; fitting the guide pin in two of the through-holes and the connection hole of the ligament reconstruction device aligned with each other, and drilling another guide pin into the articular bone through the other two through-holes of the ligament reconstruction device; removing portions of the bone around the previously-inserted two guide pins by over-drilling; and driving the tip portion of the ligament reconstruction device into the articular bone toward a lateral cortex of the articular bone by hitting the rear end portion of the ligament reconstruction device with the two guide pins respectively fitted in the two through-holes and the connection hole of the ligament reconstruction device aligned with each other and in the other two through-holes of the ligament reconstruction device to form a flat socket into which one end portion of a ligament graft is to be inserted. The flat socket has a depth of 10 to 23 mm. The ligament graft is an anterior cruciate ligament graft with a bone piece. The ligament reconstruction is reconstruction of an anterior cruciate ligament graft, and the articular bone is a femur.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffmann et al. (US Pat. 5,021,056).

Hoffman et al discloses the claimed invention except for the generally elliptical or rectangular cross section having a major axis/minor axis ratio of 2 to 5; the racetrack-like elliptical shape being defined by a pair of parallel straight lines spaced a distance of 3 to 6mm from each other and each having a length of 4 to 8mm; the rectangular cross section having a minor edge length of 3 to 6mm and a major edge length of 7 to 14mm; the tip portion having a cross sectional area of 21 to 84 mm<sup>2</sup>; the tip portion having a length of 5 to 10mm.

With regard to claims 2, 4, 5, 6 and 7, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device for ligament reconstruction of Hoffman et al. with the the generally elliptical or rectangular cross section having a major axis/minor axis ratio of 2 to 5; the racetrack-like elliptical shape being defined by a pair of parallel straight lines spaced a distance of 3 to 6mm from each other and each having a length of 4 to 8mm; the rectangular cross section having a minor edge length of 3 to 6mm and a major edge length of 7 to 14mm; the tip portion having a cross sectional area of 21 to 84 mm<sup>2</sup>; the tip portion having a length of 5 to 10mm. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

A nonstatutory provisional double patenting rejection exists between this application and copending application No. 10563915. The full double patenting rejection can be found in the Office Action regarding application No. 10563915.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Please see attached PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571)



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272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC



EDUARDO C. ROBERT  
SUPERVISORY PATENT EXAMINER